REMARKS

Claims 22-27, as amended, and new claims 28-32 are pending in this application for the Examiner's review and consideration. Claim 22 has been amended to more clearly recite the claimed embodiments. Claim 25 has been amended to recite intravenous and not for reasons related to patentability. New claims 28-32 have been amended to recite embodiments of the invention. No new matter has been added by these amendments.

I. The Objection to the Abstract

On page 2 of the office action, the Examiner has alleged that "[t]he abstract on page 32 of the specification contains more than one paragraph and exceeds 150 words. The abstract should be in a single paragraph and shall not exceed 150 words. Appropriate correction is required."

Applicants have submitted a replacement Abstract herewith thus overcoming the Examiner's objection.

II. The New Matter Objection

The Examiner alleges on pages 2-3 of the Office Action that the amendment filed 12-1-03 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. According to the office action,

> the amendment filed 12-1-03 amends the specification by inserting after the title on page 1, 'This application is a divisional of U.S. application no. 10/098,359, filed March 18, 2002, . . .the disclosures of which are incorporated herein by reference.' The added material which is not supported by the original disclosure is as follows: The oath/ declaration only claims priorities of parent applications but fails to incorporate herein by reference. Thus, the amendment filed 12-1-03 introduces new matter into the specification.

Applicants respectfully disagree with this assertion of new matter. Specifically, Applicants direct the Examiner's attention to Manual of Patent Examining Procedure ("MPEP") § 201.06(c)IV, entitled Incorporation By Reference. MPEP § 201.06(c)IV states:

> An applicant may incorporate by reference the prior application by including, in the continuation or divisional application as-filed, an explicit statement that such applications are "hereby incorporated

> by reference." The statement must appear in the specification. See 37 C.F.R. § 1.57(b) and MPEP § 608.01(p).

For at least this reason, Applicants respectfully submit that the incorporation by reference statement filed in the preliminary amendment submitted on the date the application was filed does not constitute new matter. Applicants respectfully request that the Examiner withdrawal this objection.

III. The Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 22 is rejected on pages 3-4 of the office action under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicant regards as the invention.

According to the office action, the phrase "unitary doses of viral particles" in claim 22 is vague and renders the claim indefinite. The office action alleges that "[t]he term 'unitary' means 'of or relating to a unit' or 'having the character of a unit' according to the Merrian-Webster OnLine Dictionary. However, it is unclear as to the metes and bounds of what would be considered 'unitary doses.' It is unclear how many viral particles is considered 'unitary dose.' The specification fails to specifically define the phrase 'unitary doses of viral particles.'" Applicants respectfully traverse the rejection.

Applicants direct the Examiner's attention to paragraph [0071], which teaches a non-limiting, preferred embodiment of the invention, which describes an exemplary, non-limiting unitary dose. Paragraph [0071] discloses:

> The preferred way to apply the present invention is through endovenous administration of the recombinant adenoviral vectors of this invention or the pharmaceutical compound which contains them, in which therapeutically effective amount is administered with an unitary dose regimen convenient to an individual with fibrosis. This regimen can be adjusted according to the affliction degree. Generally, unitary doses of about 10^7 to 10^{14} viral particles for individual are employed. The preparation of a pharmaceutical compound including the adenoviral recombinant vectors of this invention can be conducted through the employment of standard techniques very well known by the persons skilled in the art, in combination with any of the pharmaceutically acceptable carriers described in the state of the art, including without limitation, starch, glucose, lactose, sacharose, gel, malt, rice, wheat flour,

> chalk, silica-gel, magnesium stearate, sodium stearate, powder of glyceril monostearate, NaCl, glycerol, propilene glycol, water, ethanol, and similar. These compounds can take the pharmaceutical form of solutions, suspensions, pills, tablets, capsules, powders and slow release formula, and similar.

See Specification at paragraph [0071], our emphasis added.

Thus, the specification provides guidance to one of ordinary skill in the art what an exemplary, non-limiting unitary dose comprises, and therefore, the rejection under 35 U.S.C. 112, second paragraph, should be reconsidered and withdrawn.

IV. The Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 22-27 are rejected on pages 4-10 of the office action under 35 U.S.C. § 112, first paragraph. According to the office action, the claims contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants respectfully submit that they have amended claim 22 to overcome the rejection. Applicants respectfully request that the rejection be reconsidered and withdrawn.

V. The Rejections Under 35 U.S.C. § 102(b)

A. The Rejections

Claims 22 and 23 stand rejected on pages 11-12 of the office action under 35 U.S.C. § 102(b) as allegedly being anticipated by Hattori *et al.*, January 20, 1999 (Human Gene Therapy, Vol. 10, no. 2, pp. 215-222) ("Hattori").

Claim 22 is rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Jaffe *et al.*, April-May 1999 (Experimental Lung Research, Vol. 25, No. 3, pp. 199-215) ("Jaffe").

Applicants respectfully traverse these rejections. Applicants note that the pending application is a divisional of U.S. application number 10/098,359, filed March 18, 2002, which is a continuation of national stage designation of PCT/MX00/00035, filed September 14, 2000, which claim the benefit of Mexican application number 998515, filed September 17, 1999. Because the pending application claim priority to a Mexican application dated, September 17, 1999, the cited references are not available as prior art under 35 U.S.C. § 102(b). Applicants respectfully request that the rejections be reconsidered and withdrawn.

VI. Conclusions

It is respectfully submitted that the rejections to the claims have been overcome. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

No fees are believed to be required for this submission. Should any fees be required, however, please charge those fees to Morgan, Lewis & Bockius LLP deposit account no. 50-0310.

Respectfully submitted,
Morgan, Lewis & Bockius LLP

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Dated: February 7 , 2006
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